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Docket No.: BOLTON 1042

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By: Steven E. Keen Date: December 18, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Before the Board of Patent Appeals and Interferences

Applic. No.	:	10/784,462	Conf. No. 8228
Applicant	:	Humberto Berra et al.	
Filed	:	February 23, 2004	
Title	:	Stent Graft	
Group Art Unit	:	3731	
Examiner	:	Brian E. Pellegrino	
Docket No.	:	Bolton 1042	
Customer No.	:	27,316	

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BRIEF ON APPEAL

S i r :

This is an appeal from the final rejection in the July 17, 2006 Office action, finally rejecting claims 1 to 6, 10 to 21 , 24 to 29, 40 to 60, 65 to 67, 70 to 72, 75 to 77, 80 to 82, 85 to 87, 90 to 92, and 95 to 97.

Appellants submit one copy of this *Brief on Appeal* pursuant to MPEP 1205.02. The fee for filing the *Brief on Appeal* in the amount of $500.00 is enclosed. Please charge any other fees that might be due to the Deposit Account of Mayback & Hoffman, P.A., No. 503,836.

Real Party in Interest:

This application is assigned to Bolton Medical, Inc., of Sunrise, Florida, USA. The assignment is on file under Reel 015257, Frame 0867, and Reel 015532, Frame 0234.

Related Appeals and Interferences:

No related appeals or interference proceedings are currently pending which would directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

Status of Claims:

Claims 1 to 109 remain in the application.

Claims 1 to 6, 10 to 21, 24 to 29, 40 to 60, 65 to 67, 70 to 72, 75 to 77, 80 to 82, 85 to 87, 90 to 92, and 95 to 97 are rejected and are under appeal.

Claims 7 to 9, 22, 23, 30 to 39, 61 to 64, 68, 69, 73, 74, 78, 79, 83, 84, 88, 89, 93, 94, and 98 to 109 have been withdrawn from examination.

Status of Amendments:

No claims were amended after the final Office action.

A *Response* under 37 CFR § 1.116 was filed on September 18, 2006, and, after discovering errors in that Response, a Supplemental Response was filed on October 6, 2006, after speaking with the Examiner that such a supplement was to be filed. The Examiner stated in an *Advisory Action* dated October 12, 2006, that the request for reconsideration had been considered but did not place the application in condition for allowance. In an attempt to point out clear errors in the Final rejection, Appellants conducted an interview with the Examiner, which interview was summarized in an Interview Summary mailed December 5, 2006.

Summary of the Claimed Subject Matter:

As stated in the first paragraph on page 1 of the specification of the instant application, line 10, the invention lies in the field of endoluminal blood vessel repairs. The invention specifically relates to a stent graft used for endoluminally repairing aneurysm and/or dissections of the thoracic transverse aortic arch, thoracic posterior aortic arch, and the descending thoracic portion of the aorta.

Appellants explained on page 23 of the specification, line 6, that the present invention provides a stent graft and delivery system that treats, in particular, thoracic aortic defects from the brachiocephalic level of the aortic arch distally to a level just superior to the celiac axis and provides an endovascular foundation for an anastomosis with the thoracic aorta, while providing an alternative method for partial/total thoracic aortic repair by excluding the vessel defect and making surgical repair of the aorta unnecessary. The stent graft of the present invention, however, is not limited to use in the aorta. It can be endoluminally inserted in any accessible artery that could accommodate the stent graft's dimensions.

Appellants outlined on page 23 of the specification, line 15, that, the stent graft according to the present invention provides various features that, heretofore, have not been applied in the art and, thereby, provide a vessel repair device that implants/conforms more efficiently within the natural or diseased course of the aorta, decreases the likelihood of vessel puncture, and increases the blood-tight vascular connection, and decreases the probability of graft mobility.

It is further stated on page 22 of the specification, line 5, that, the stent graft is implanted endovascularly before or during or in place of an open repair of the vessel (i.e., an arch, in particular, the ascending and/or descending portion of the aorta) through a delivery system described in detail below. The typical defects treated by the stent graft are aortic aneurysms, aortic dissections, and other diseases such as penetrating aortic ulcer, coarctation, and patent ductus arteriosus, related to the aorta. When endovascularly placed in the aorta, the stent graft forms a seal in the vessel and automatically affixes itself to the vessel with resultant effacement of the pathological lesion.

It is described on page 23 of the specification, line 5, that, FIG. 1 shows an improved stent graft 1 having a graft sleeve 10 and a number of stents 20. These stents 20 are, preferably, made of nitinol, an alloy having particularly special properties allowing it to rebound to a set configuration after compression, the rebounding property being based upon the temperature at which the alloy exists. For a detailed explanation of nitinol and its application with regard to stents, see, i.e., United States Patent Nos. 4,665,906, 5,067,957, and 5,597,378 to Jervis and to Gianturco.

Appellants outlined on page 23 of the specification, line 13, that the graft sleeve 10 is cylindrical in shape and is made of a woven graft material along its entire length. The graft material is, preferably, polyester, in particular, polyester referred to under the name DACRON®

or other material types like Expanded Polytetrafluoroethylene ("EPTFE"), or other polymeric based coverings. The tubular graft sleeve 10 has a framework of individual lumen-supporting wires each referred to in the art as a stent 20. Connection of each stent 20 is, preferably, performed by sewing a polymeric (nylon, polyester) thread around an entirety of the stent 20 and through the graft sleeve 10. The stitch spacings are sufficiently close to prevent any edge of the stent 20 from extending substantially further from the outer circumference of the graft sleeve 10 than the diameter of the wire itself. Preferably, the stitches have a 0.5 mm to 5 mm spacing.

As set forth on page 23, line 23, the stents 20 are sewn either to the exterior or interior surfaces of the graft sleeve 10. FIG. 1 illustrates all stents 20, 30 on the exterior surface 16 of the graft sleeve 10. In a preferred non-illustrated embodiment, the most proximal 23 and distal stents and a bare stent 30 are connected to the interior surface of the graft sleeve 10 and the remainder of the stents 20 is connected to the exterior surface 16. Another possible non-illustrated embodiment alternates connection of the stents 20, 30 to the graft sleeve 10 from the graft exterior surface to the graft interior surface, the alternation having any periodic sequence.

It is further stated on page 25 of the specification, line 7, that a stent 20, when connected to the graft sleeve 10, radially forces the graft sleeve 10 open to a predetermined diameter D. The released radial force creates a seal with the vessel wall and affixes the graft to the vessel wall when the graft is implanted in the vessel and is allowed to expand.

Appellants outlined in the last paragraph on page 25 of the specification that, typically, the stents 20 are sized to fully expand to the diameter D of the fully expanded graft sleeve 10. However, a characteristic of the present invention is that each of the stents 20 and 30 has a diameter larger than the diameter D of the fully expanded graft sleeve 10. Thus, when the stent graft 1 is fully expanded and resting on the internal surface of the vessel where it has been

placed, each stent 20 is imparting independently a radially directed force to the graft sleeve 10. Such pre-compression, as it is referred to herein, is applied (1) to ensure that the graft covering is fully extended, (2) to ensure sufficient stent radial force to make sure sealing occurs, (3) to affix the stent graft and prevent it from kinking, and (4) to affix the stent graft and prevent migration.

Appellants also outlined on page 25 of the specification, line 21, that, preferably, each of the stents 20 is formed with a single nitinol wire. Of course other biocompatible materials can be used, for example, stainless steel, biopolymers, cobalt chrome, and titanium alloys.

Appellants stated in the first paragraph of page 26 of the specification that the preferred shape of each stent 20 corresponds to what is referred in the art as a Z-stent, see, i.e., Gianturco (although the shape of the stents 20 can be in any form that satisfies the functions of a self-expanding stent). Thus, the wire forming the stent 20 is a ring having a wavy or sinusoidal shape. In particular, an elevational view orthogonal to the center axis 21 of the stent 20 reveals a shape somewhere between a triangular wave and a sinusoidal wave as shown in FIG. 2. In other words, the view of FIG. 2 shows that the stents 20 each have alternating proximal 22 and distal 24 apices. Preferably, the apices have a radius r that does not present too great of a point towards a vessel wall to prevent any possibility of puncturing the vessel, regardless of the complete circumferential connection to the graft sleeve 10. In particular, the radius r of curvature of the proximal 22 and distal 24 apices of the stent 20 are, preferably, equal. The radius of curvature r is between approximately 0.1 mm and approximately 3.0 mm, in particular, approximately 0.5 mm.

Appellants outlined on page 26, line 14, that another advantageous feature of a stent lies in extending the longitudinal profile along which the stent contacts the inner wall of a vessel. This longitudinal profile can be explained with reference to FIGS. 3 to 7.

Appellants explained on page 26, line 17, that prior art stents and stents according to the present invention are formed on mandrels 29, 29' by winding the wire around the mandrel 29,